GEORGIA DEPARTMENT OF COMMUNITY HEALTH

ANTIFUNGALS PA SUMMARY

Preferred	Non-Preferred
Oral	
Clotrimazole oral troche generic Fluconazole tablets, oral suspension generic Flucytosine generic Itraconazole capsules generic Gris-PEG (griseofulvin ultramicrosize) Sporanox oral solution (itraconazole) Terbinafine tablets generic	Griseofulvin microsize generic Griseofulvin ultramicrosize generic Lamisil oral granules (terbinafine) Noxafil DR, suspension (posaconazole) Onmel (itraconazole) Terbinex kit (terbinafine 250 mg tablets [42 tablets], hydroxyprop chitosan 12 ml) Vfend (voriconazole suspension) Voriconazole suspension, tablets (generic)
Injection	
Fluconazole generic	Vfend (voriconazole) Voriconazole generic
Topical	
Ciclopirox 8% nail lacquer (solution) Ciclopirox cream, suspension generic Econazole cream generic Ketoconazole cream, shampoo generic Miconazole generic Nystatin cream and ointment generic	Ciclodan Kit (ciclopirox 8% solution) Ciclodan Cream Kit (ciclopirox cream 0.77%, cleanser) CNL8 Nail Kit (ciclopirox 8% solution) Ciclopirox gel, shampoo generic Ertaczo (sertaconazole) – *PA not required* Exelderm (sulconazole) – *PA not required* Extina foam (ketoconazole 2%) Jublia (efinaconazole) Kerydin (tavaborole) Ketoconazole 2% foam Ketodan Kit (ketoconazole 2% foam, cleanser) Loprox shampoo (ciclopirox) Luzu (luliconazole) Mentax (butenafine) – *PA not required* Naftin (naftifine) Nystatin/triamcinolone cream and ointment generic Oxistat (oxiconazole) – *PA not required* Pediaderm AF Kit (nystatin cream and diaper rash cream) - *covered only for members <21 years of age* Pedipirox-4 Nail (ciclopirox 8% solution) Vusion (miconazole/petrolatum/zinc oxide)

LENGTH OF AUTHORIZATION: Varies based on drug and diagnosis

NOTE: If generic ketoconazole foam is approved, the PA will be issued for brand Extina. If generic ciclopirox shampoo is approved, the PA will be issued for brand Loprox shampoo. If generic voriconazole suspension is approved, the PA will be issued for brand Vfend suspension.

Revised 2/15/2015

PA CRITERIA:

For ciclopirox 8% generic, CNL8, Ciclodan Kit, or Pedipirox-4 Nail

- Approvable for the treatment of mild to moderate onychomycosis or white superficial onychomycosis in members with diabetes mellitus or peripheral vascular disease. Member must have a positive fungal culture result.
- Approvable for the treatment of moderate to severe onychomycosis in members with diabetes mellitus, peripheral vascular disease, or immunocompromised status. Member must have a positive fungal culture result AND must have experienced ineffectiveness, allergies, drug-drug interactions, contraindications, or a history of intolerable side effects to terbinafine (Lamisil).
- CNL8, Ciclodan Kit, and Pedipirox-4 Nail also require a written letter of medical necessity stating the reason(s) that generic ciclopirox nail lacquer cannot be used.

For Jublia or Kerydin

- Approvable for the treatment of onychomycosis in members with diabetes mellitus, peripheral vascular disease, or immunocompromised status.
- Member must have a positive fungal culture result AND must have experienced ineffectiveness, allergies, drug-drug interactions, contraindications, or a history of intolerable side effects to terbinafine and ciclopirox 8% solution.

For fluconazole injection

- Medication must be administered in member's home by home health or in a long-term care facility.

For griseofulvin microsize (generic), griseofulvin ultramicrosize (generic)

- Submit a written letter of medical necessity stating the reason(s) that brand-name Gris-PEG (preferred product) is not appropriate for the member.

For itraconazole capsules

- Approvable for the treatment of onychomycosis. Member must have experienced ineffectiveness, allergies, drug-drug interactions, contraindications, or a history of intolerable side effects to terbinafine (Lamisil) AND must have a positive KOH preparation, fungal culture, or nail biopsy.
- Approvable for the diagnosis of aspergillus, blastomycosis, or histoplasmosis.
- Approvable for the diagnosis of tinea versicolor, tinea cruris, tinea corporis, or tinea pedis when infections involve a large area of the body or the member is immunocompromised or when member has tried and failed at least one OTC or prescription topical antifungal agent.

For Lamisil oral granules

- Approvable for the treatment of tinea capitis in members 4-12 years of age. Member must have experienced ineffectiveness, allergies, drug-drug

interactions, contraindications, or a history of intolerable side effects to griseofulvin.

For Noxafil (solution or DR tablets)

- Noxafil is approvable for the following diagnoses:
  - Preventative therapy for invasive aspergillus and/or candida in immunocompromised members
  - Invasive aspergillosis, zygomycosis, fusariosis, or other moulds that are resistant to previous systemic antifungal therapy
- Noxafil is also approvable for oropharyngeal candidiasis refractory to itraconazole or fluconazole *OR* for members with allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to itraconazole or fluconazole.
- Noxafil is also approvable for continuation of therapy following discharge from a hospital for certain diagnoses.

For Onmel

- Approvable for the treatment of onychomycosis.
- Prescriber should submit a written letter of medical necessity stating the reason(s) the preferred product itraconazole capsules, which also requires PA, is not appropriate for the member.

For Sporanox oral solution

- Approvable for the diagnosis of oropharyngeal candidiasis (thrush), esophageal candidiasis, or empiric febrile neutropenia.
- Approvable in patients meeting Sporanox capsules or pulsepak criteria who are unable to swallow capsules.

For Terbinex Kit

- Terbinafine tablets are preferred and also require PA. If terbinafine tablets cannot be used, submit a written letter of medical necessity detailing reason(s).

For Vfend (suspension or IV) or voriconazole (suspension, tablets, IV)

- Approvable for members using oral Vfend (voriconazole) for continuation of therapy after being started on IV Vfend therapy.
- Approvable for members who have tried one other systemic antifungal agent and who have one of the following diagnoses:
  - Esophageal candidiasis
  - Candidemia in nonneutropenic patient
  - Disseminated Candida skin infection
  - Candida infection in abdomen, kidney, bladder wall, or wound
- Approvable for members with invasive aspergillus, fungal infection caused by Scedosporium apiospermum, or fungal infection caused by Fusarium species.
- Approvable for prophylaxis of aspergillosis or candida in severely immunocompromised patients.
- Approvable for CNS blastomycosis. Member must have experienced ineffectiveness, allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to itraconazole.

- ❖ Additionally, Vfend IV must be administered in a member's home by home health or in a long-term care facility and must require IV Vfend therapy versus oral Vfend therapy.

For Ciclodan Kit

- ❖ Submit a written letter of medical necessity stating the reason(s) that generic ciclopirox cream 0.77% (preferred medication) is not appropriate for the member.

For Ciclopirox Gel

- ❖ Submit a written letter of medical necessity stating the reason(s) that brand-name Loprox gel 0.77% (preferred medication) is not appropriate for the member.

For Naftin

- ❖ Member must have experienced trial and failure of at least one OTC or prescription topical antifungal agent that does not require prior authorization.

For Ketoconazole Foam or Ketodan Kit

- ❖ Approvable for members age 12 or older with a diagnosis of seborrheic dermatitis.
- ❖ Provider should submit a written letter of medical necessity stating the reason(s) the preferred product, generic ketoconazole cream or shampoo, is not appropriate for the member.

For Loprox (Ciclopirox) Shampoo

- ❖ Approvable for the diagnosis of seborrheic dermatitis
- ❖ Member must have experienced ineffectiveness, allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to generic ketoconazole shampoo.

For Luzu

- ❖ Approvable for members age 18 or older with a diagnosis of tinea corporis, tinea cruris, or tinea pedis confirmed by KOH (potassium hydroxide preparation) or cell culture test.
- ❖ Member must have tried and failed at least one OTC or prescription topical antifungal agent.

For Pediaderm AF Kit

- ❖ Submit a written letter of medical necessity stating the reason(s) the two separate products (nystatin cream and OTC diaper rash cream) are not appropriate for the member.

For Vusion

- ❖ Approvable for members age 4 weeks or older with a diagnosis of diaper dermatitis when the presence of a candidal infection has been confirmed by a microscopic evaluation.
- ❖ Member must have experienced trial and failure of a topical antifungal agent (OTC or prescription) within the past 60 days.

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QLL CRITERIA FOR SPORANOX (ITRACONAZOLE) CAPSULES OR PULSEPACK (QLL IS SET AT 60/30 DAYS):

- An authorization to exceed the QLL may be granted for members with aspergillus, blastomycosis, or histoplasmosis.

EXCEPTIONS:

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **Catamaran at 1-866-525-5827.**

PA and APPEAL PROCESS:

- For online access to the PA process, please go to www.dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

- For online access to the current Quantity Level Limits (QLL), please go to www.mmis.georgia.gov/portal, highlight Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services and select that manual.